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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Stephen Martone

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P.O. Box 16446

Arlington, VA 22215

EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT

PAPER NUMBER

3739

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,927	Applicant(s) MARTONE ET AL.	
	Examiner MATTHEW J. KASZTEJNA	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-50 and 73-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-50 and 73-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 February 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/26/10, 4/28/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on June 24, 2010, amended claim 1 and new claims 92-93 are acknowledged. The following new and reiterated grounds of rejection are set forth:

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the following features must be shown or the feature(s) canceled from the claim(s). No new matter should be entered:

- “internal and external sheath connected non-symmetrically” (claim 46)
- “sheaths coextend at their distal ends, such that their distal ends extend to a same point” (claims 49 and 93)
- “wherein over most of the length of the sheath assembly, the external sheath is attached to the internal sheath along at least one longitudinal line” (claim 77)
- “wherein over most of the length of the sheath assembly, the external sheath is not attached to the internal sheath” (claim 78)
- “wherein the external and the internal sheath are connected to a proximal connector” (claim 79). It is noted a connector 110 is shown, but the sheaths are not shown to be connected to the connector in any fashion or manner.
- “wherein the external sheath is sealed at its distal end” (claim 81)

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Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 93 is objected to because of the following informalities: claim 93 is identical to claim 49. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 43-50 and 73-93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "sheathed probe" in line 8 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 44-50 and 73-93 are rejected as being necessarily dependant thereon.

The term "over most of the length" in claims 77-78 is a relative term which renders the claim indefinite. The term "over most of" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It unclear how much of the internal sheath is actually being covered by the external sheath by current indifferently wording in the recited claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 43-45, 47, 49, 73-77, 79, 82-84, 87 and 91-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakao et al. (U.S. Patent 5,217,001).

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In regard to claim 43, Nakao discloses a sheath (Figs. 7-10) assembly for a probe, comprising: an internal sheath (80) configured to isolate a probe from body fluids; and an external sheath (94) surrounding the internal sheath, the external sheath *configured to* define a channel for passing fluids, tools or working tubes and the internal and external sheaths being connected to each other, wherein the internal sheath is bendable, *configured to* bend longitudinally around corner *while* the sheathed probe is inserted into a patient and wherein the external sheath is folded *during* insertion into the body (see Fig. 9). It is noted that the words “configured to” in the claim may be properly interpreted as “capable of,” and “capable of” does not require that reference actually teach the intended use of the element, but merely that the reference does not make it so it is incapable of performing the intended use.

In regard to claim 44, Nakao discloses that the internal and external sheaths are connected to each other over at least one axial line (Col. 8, lines 39-44) extending over a segment of the length of the sheaths.

In regard to claim 45, Nakao discloses that the internal and external sheaths are connected over at least two longitudinal lines (see Figs. 7 & 9).

In regard to claim 47, Nakao discloses that the internal and external sheaths are connected radially symmetrically (Fig. 9).

In regard to claims 49 and 93, Nakao discloses that the internal and external sheaths coextend at their distal ends, such that their distal ends extend to a same point (Fig. 8).

In regard to claim 73, Nakao discloses that there is at least one channel is defined between the external sheath and the internal sheath along at least a portion of the sheath assembly (Fig. 10).

In regard to claim 74, Nakao discloses that the at least one channel is open at the distal end of the sheaths (Col. 8, lines 39-43).

In regard to claim 75, Nakao discloses that the channel does not surround the entire internal sheath (Fig. 10).

In regard to claim 76, Nakao discloses that there are two channels (channels with 97 and 99, Fig. 10).

In regard to claim 77, Nakao discloses that the over most of the length of the sheath assembly, the external sheath is attached to the internal sheath along at least one longitudinal line (Figs. 7 & 10, Col. 8, lines 39-43).

In regard to claim 79, Nakao discloses that the external sheath and the internal sheath are connected to a proximal connector (92, Fig. 8).

In regard to claim 82, Nakao discloses that the internal sheath comprises an imaging window (opening through which the optics 81 can be seen, Fig. 8) at its distal end.

In regard to claim 83, Nakao discloses wherein the internal and external sheaths are foldable. Foldable merely means capable of being folded and thus Nakao meets the limitations of the claims.

In regard to claim 84, Nakao discloses that the internal and external sheaths can be bent (Fig. 9 and Fig. 10 where it can be seen the external sheath being bent from expanded to collapsed, Col. 8, lines 11-15, wherein “rubber” is bendable).

In regard to claim 87, Nakao discloses a sheath assembly wherein the internal and external sheaths have *substantially* the same thickness (see Figs. 9-11). The term “substantially” in the claim is a relative term and as broadly as claimed Nakao shows internal and external sheaths that are *substantially* the same.

In regard to claim 91, Nakao discloses two longitudinal lines which define a plurality of separate channels between the sheaths (Fig. 7).

In regard to claim 92, Nakao discloses a sheath assembly, wherein the external sheath extends over at least 50% of the internal sheath (Fig. 7).

Claims 43, 46, 80, 85, and 90 are rejected under 35 U.S.C. 102(b) as being unpatentable over Bacich et al. (U.S. Patent 5,749,889).

In regard to claim 43, Bacich discloses a sheath (Fig. 3) usable for a probe comprising: an internal sheath (132) configured to isolate a probe from body fluids; and an external sheath (140) surrounding the internal sheath, the external sheath *configured to* define a channel for passing fluids, tools or working tubes and the internal and external sheaths being connected to each other, wherein the internal sheath is bendable, *configured to* bend longitudinally around corner *while* the sheathed probe is inserted into a patient and wherein the external sheath is folded *during* insertion into the body. It is noted that the words “configured to” in the claim may be properly interpreted as “capable of,” and “capable of” does not require that reference actually teach the

intended use of the element, but merely that the reference does not make it so it is incapable of performing the intended use.

In regard to claim 46, Bacich discloses that the internal and external sheaths are connected non-symmetrically radially (Figs. 3 & 4, where it can be seen that there the outer membrane is connected differently to the inner sheath at section 136).

In regard to claim 80, Bacich discloses that the external sheath is formed with an internal notch capable of receiving a dovetail of a working tube (144).

In regard to claim 85, Bacich discloses that the external sheath is non-elastic (Col. 14, lines 25-29).

In regard to claim 90, Bacich discloses that the external sheath is non- self collapsible (Col. 14, lines 8-12).

Claims 43, 48, 50, 78, 81, and 86 are rejected under 35 U.S.C. 102(b) as being unpatentable over Krasner et al. (U.S. Patent 4,676,228).

In regard to claim 43, Krasner discloses a sheath (Fig. 3) usable for a probe comprising: an internal sheath (46) configured to isolate a probe from body fluids; and an external sheath (18) surrounding the internal sheath, the external sheath *configured to* define a channel for passing fluids, tools or working tubes and the internal and external sheaths being connected to each other, wherein the internal sheath is bendable, *configured to* bend longitudinally around corner *while* the sheathed probe is inserted into a patient and wherein the external sheath is folded *during* insertion into the body. It is noted that the words “configured to” in the claim may be properly interpreted as “capable of,” and “capable of” does not require that reference actually teach the

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intended use of the element, but merely that the reference does not make it so it is incapable of performing the intended use.

In regard to claim 48, Krasner discloses that the internal and external sheaths are connected substantially only at plurality of circumferential points at a distal end of the external sheath (Fig. 3, connected by 44a).

In regard to claim 50, Krasner discloses that the internal sheath extends beyond the distal end of the external sheath (Fig. 3).

In regard to claim 78, Krasner discloses that over most of the length of the sheath assembly, the external sheath is not attached to the internal sheath (Fig. 3).

In regard to claim 81, Krasner discloses that the external sheath is sealed at its distal end (at 44a, Fig. 3).

In regard to claim 86, Krasner's external sheath is stretchable (as it is made of urethane, Col. 6, lines 52-56).

Claims 43, 48 and 88 are rejected under 35 U.S.C. 102(e) as being anticipated by Oneda et al. (U.S. Patent 6,461,294).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

In regard to claim 43, Oneda discloses a sheath assembly (Fig. 3) comprising an internal sheath (103) configured to isolate a probe from body fluids; and an external sheath (300/400/500) surrounding the internal sheath, the external sheath *configured to* define a channel for passing fluids, tools or working tubes and the internal and external sheaths being connected to each other, wherein the internal sheath is bendable, *configured to* bend longitudinally around corner *while* the sheathed probe is inserted into a patient and wherein the external sheath is folded *during* insertion into the body. It is noted that the words “configured to” in the claim may be properly interpreted as “capable of,” and “capable of” does not require that reference actually teach the intended use of the element, but merely that the reference does not make it so it is incapable of performing the intended use.

In regard to claim 48, Oneda discloses that the internal and external sheaths are connected substantially only at plurality of circumferential points at a distal end of the external sheath (connected at 340, Fig. 3).

In regard to claim 88, Oneda discloses internal and external sheaths formed of the same material (see Col. 4, Lines 20-25 and Col. 4, Lines 50-57).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

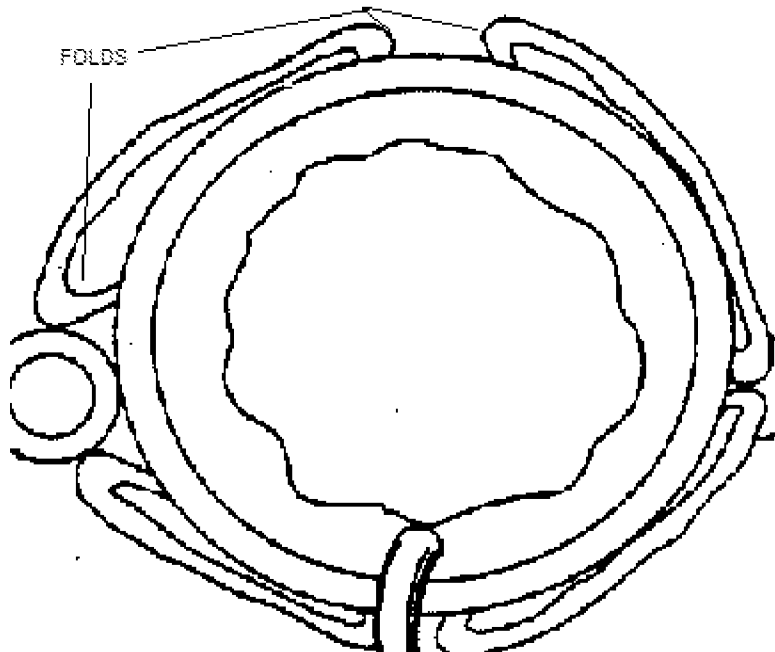
Claim 89 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oneda et al. (U.S. Patent 6,461,294) in view of Oneda et al. (U.S. patent 6,174,280).

In regard to claim 89, Oneda '294 discloses a sheath assembly comprising internal and external sheaths (see rejections above) but are silent with respect to a rigid pipe section located at the proximal end of the internal sheath. Oneda '280 discloses a sheath for a probe (Figs. 7-8) which serves to protect the probe while altering the bending characteristics of the probe with a rigid member (241) adhered to a proximal region of the sheath. This rigid member gives the ability of the operator to change the bending characteristics of the probe and therefore "allows one endoscope to be used effectively and efficiently for a range of procedures which typically require insertion tubes with different bending characteristics" (Col. 2, lines 50-54). It therefore would have been obvious to one of ordinary skill in the art to modify Oneda's ('294) internal sheath so that it had this rigid member in order to give it the advantages taught by Oneda '280, as noted above.

Response to Arguments

Applicant's arguments filed June 24, 2010 have been fully considered but they are not persuasive.

Applicant states that Nakao fails to teach of an external channel which is folded during insertion into the body. Examiner disagrees. As clearly seen in Figure 9, the external sheath is folded during insertion into the body (see also Col.8, Lines 39-63).



Applicant states that Bacich et al. fail to teach of an internal sheath that is bendable. Examiner disagrees. Firstly as seen in figures 1-2, the entire insertion portion 102 of Bacich et al is shown to be bent, and thus both internal and external sheath are “bendable”. Bendable is an extremely relative term, and any sheath inherently has a certain degree of bendability and/or foldability (as recited in claim 83). Furthermore, term “bendable” in the claim may be properly interpreted as “capable of being bent,” and “capable of bending” does not require that reference actually teach the intended use of the element, but merely that the reference does not make it so it is incapable of performing the intended use. The terms “bendable” and “foldable” fail to positively provide any structural limitations to the claim nor do they lend any patentable or novel features to the claims. In response to applicant's argument that “the internal sheath is not configured to bend longitudinally around corners while inserted into a

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patient”, it is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim (It is also noted, that nowhere in the specification is it disclosed that the internal sheath is bent longitudinally around corners). Regardless, Bacich et al. clearly show bent internal and external sheaths (See Figs. 1-2) and thus as broadly as claimed, meet the current limitations of the claims.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., passing fluid, tools or working tubes through an external sheath) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claim fails to positively recite passing fluids, tools or working tubes through the external sheath. Applicant states that both Krasner et al. and Oneda et al. are not *configured to* define a channel *for* passing of fluids tools or working tubes. Again, the words “configured to” and “for” in the claim may be properly interpreted as “capable of,” and “capable of” does not require that reference actually teach the intended use of the element, but merely that the reference does not make it so it is incapable of performing the intended use. Furthermore, the external sheaths of both Krasner et al. and Oneda et al. are used for inflation to assist a user in navigating and /or maintaining a location of the endoscope within the body (as

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stated in applicant's arguments, pg 10). The sheaths are inflated and deflated with a "fluid", and thus as broadly as claimed, both external sheaths define a channel for passing a fluid. If either sheath failed to define a channel through which fluid (i.e. an inflation medium) could pass through, then each sheath assembly would be rendered useless and the main objective of navigating (Krasner) or maintaining (Oneda) an endoscope within the body would be defeated. Therefore, Krasner et al. and Oneda et al. meet the current limitations of the claims.

Applicant's arguments with respect to claims 87-89 and 92-93 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew J Kasztejna/
Primary Examiner, Art Unit 3739

7/28/10